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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,403	07/02/2001	Kenneth William Hunt	004565-067	9206

21839 7590 09/10/2003

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EXAMINER

TRUONG, LINH T

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 09/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,403

Applicant(s)

HUNT ET AL.

Examiner

Linh Truong

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the **abstract not exceed 150 words in length** since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lina et al. (Lina) 'EPO 0 853 950.

For claims 8 and 9, Lina teaches a wound drainage apparatus comprising an open-celled pad 36, suction tubes 37,38 connecting the pad 36 to a collection canister 19, a tube 62 connecting the canister 19 to a vacuum pump and that is capable of

connecting the canister to a wall suction point or a vacuum bottle (col. 2, lines 43-51) and a fill sensor 64 for sensing when the container is filled and shutting off the vacuum (col. 12, lines 13-19).

For claim 10, Lina teaches a transducer 75 to measure the pressure at the wound site (col.11, lines 15-41).

For claim 11, teaches a keypad that have various vacuum pressures that a user can choose (col. 9, lines 35-46) over the pressure that is presently displayed/present between the canister and the vacuum source.

Claims 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunt et al. 'WO 9718007 (IDS).

For claims 8-9, Hunt et al. disclose a wound drainage apparatus comprising an open-celled pad 102 (pg. 9, lines 8-9), suction tube 101 connecting pad 102 to a collection canister 100, a tube 103 connecting the canister 100 to a vacuum pump 6 and that is capable of connecting the canister to a wall suction point or a vacuum bottle (col. 2, lines 43-51), and a transducer 105 that detects pressure change when the hydrophobic filter is blocked and, thus, detects when the canister is filled and can also automatically shut off the working of the vacuum pump (pg. 6, lines 6-11).

For claim 10, Hunt et al. teaches a second tube 106 connected to the wound site 102 at one end and also to a pressure relief valve 8 for regulating pressure between the canister 100 and the suction source (pg. and to a second transducer 108 which measures the pressure at the wound site (pg. 5, lines 22-26)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. (Lina) 'EPO 0 853 950 in view of Cover et al. '5,899,884.

For claim 11, in addition to the relevant 102 rejection above, Lina does not teach a flow regulator. Flow regulators are commonly used in the art to control the flow of pressure between the suction source and the canister. Cover et al. teach a flow regulator that is meant for connecting to a vacuum source and to a device that needs pressure control (col. 2, lines 35-42) for removing bodily fluids. Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the wound drainage apparatus of Lina with the flow regulator of Cover et al. for regulating pressure between the canister and the suction source.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al. 'WO 9718007 in view of Cover et al. '5,899,884.

For claim 11, in addition to the relevant 102 rejection above, Hunt et al. do not teach a flow regulator. Flow regulators are commonly used in the art to control the flow of pressure between the suction source and the canister. Cover et al. teach a flow regulator that is meant for connection to a vacuum source and to a device that needs pressure control (col. 2, lines 35-42) for removing bodily fluids. Therefore, it is obvious

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to one with ordinary skill in the art at the time the invention was made to provide the wound drainage apparatus of Hunt et al. with the flow regulator of Cover et al. for regulating pressure between the canister and the suction source.

Claims 1 and 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. (Lina) 'EPO 0 853 950 in view of Nichols '4,256,109 and in further view of Hunt et al. 'WO 9718807.

For claim 1, Lina teaches a wound drainage apparatus comprising an open-celled pad 36, suction tubes 37,38 connecting the pad 36 to a collection canister 19, a tube 62 connecting the canister 19 to a vacuum pump and that is capable of connecting the canister to a wall suction point or a vacuum bottle (col. 2, lines 43-51) but does not teach a shut-off valve or a pressure detecting means. Shut-off valves are commonly used in wound drainage to prevent overflowing and Nichols teach a shut off valve for a medical suction canister (col. 4, lines 50-62). Hunt et al. teach a wound drainage apparatus with a transducer 105 that detects the pressure in suction tube 103 (pg. 5, lines 19-21). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the wound drainage canister of Lina with: 1) the shut off valve of Nichols for closing the canister when it is full to prevent backflow into the suction tube and flow of liquid into the vacuum pump and 2) the transducer of Hunt et al. in order to detect sub-optimal pressure levels in the suction tube for safe and efficient wound fluid suction.

For claim 3, in addition to the rejection above, Lina and Nichols together do not teach a pressure relief valve. Pressure relief valves are well known in the art to relieve

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pressure. Hunt et al. teaches a pressure relief valve 8 between the canister 100 and the vacuum source 6 for relieving pressure at the wound site (fig. 1 and pg. 6, lines 12-14) instead of between the pad 102 and the canister 100. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the relief valve between the pad 102 and canister 100, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japiske*, 86 USPQ 70. Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the wound drainage canister of Lina with the pressure relief valve of Hunt et al. in order to bring the pressure at the wound site back to atmospheric pressure rapidly when needed.

For claim 4, in addition to the two rejections above, Lina and Nichols together do not teach two transducers. It is common in the aspiration art to measure/monitor the pressure in the suction tube and the suction at the wound site for safe and effective wound drainage/treatment. Hunt et al. teaches two transducers (105 and 108); transducer 105 measures the pressure level in suction tube 103 (pg. 6, lines 6-8) and transducer 108 detects the suction level at the wound site (pg. 5, lines 24-26). Therefore, it is obvious to one with ordinary skill in the art to provide the wound drainage apparatus of the combined inventions with two transducers for monitoring the suction levels in both the suction tube and at the wound site for safe and effective wound treatment.

For claims 5-7, Lina teaches a fill sensor 64 on the exterior of chamber 18 adjacent to canister 19 that reads a sensing profile 64A (a.k.a as an electrical

capacitance device) to determine if the canister is filled or not (col. 7, lines 46- col. 8, line 5). This is also inherently a means to measure the flow rate at which the canister is filled.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. (Lina) 'EPO 0 853 950 in view of Nichols '4,256,109 and in further view of Hunt et al. 'WO 9718807 and in further view of Dixon et al. '5,944,703.

In addition to the 103 (a) rejection of claim 1 above, the combined inventions of Lina, Nichols, and Hunt et al. do not teach a flow limiting valve between the canister and suction source. It is well known in the aspiration art to have a flow limiting valve for regulating the flow of vacuum. For instance, Dixon et al. teaches a wound drainage canister 10 with an outlet port 25 connected to a vacuum source and a check valve 26 for limiting the flow of suction into the canister. Therefore, it is obvious to one with ordinary skill in the art to provide the wound drainage apparatus of the combined inventions with a check valve in the outlet 44 (this connects to tube 62 that connects to the vacuum source) to limit the flow of air into the canister for more flow conditions/ options.

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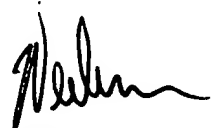
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 706-605-4974. The examiner can normally be reached on M-F 8:30am-5pm.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Linh Truong

L.T.


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